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(54) Title: BIOLOGICAL REAGENTS AND METHODS TO VERIFY THE EFFICIENCY OF SAMPLE PREPARATION AND NUCLEIC ACID AMPLIFICATION AND/OR DETECTION

(57) Abstract: This invention relates to reagent comprising: any one of cells, viral particles, organelles, parasites, cells comprising organelles, cells comprising viral particles, cells comprising parasites, cells comprising bacterial cells and any combination thereof, the cells, viral particles, organelles or parasites comprising at least one nucleic acid sequence serving as an internal control (IC) target for nucleic acid testing (NAT) assay; wherein the reagent is suitable to be added to a test sample undergoing sample preparation to release, concentrate and/or purify nucleic acids and amplification and/or detection of nucleic acids so as to be used to verify: (i) the efficiency of sample preparation; and (ii) the efficiency of nucleic acid amplification and/or detection. The present invention also relates to a method to verify or validate the preparation and amplification and/or detection of a nucleic acid target sequence in a sample spiked with a reagent of the present invention.

# INTERNATIONAL SEARCH REPORT

Intern: application No  
PCT/CA 03/01925

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, PAJ, EMBASE, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/18635 A (JONES ELIZABETH LOUISE ; BERG EINAR SVERRE (NO); STATENS INST FOR FOLK) 7 March 2002 (2002-03-07) pages 5-7, line 3 page 18, lines 27-35 page 19, line 20 - page 20, line 22 page 29, line 34 - page 30, line 12 page 33, line 31 - page 34, line 21 ----- -/-	1-4, 6-19, 23-32
Y		20-22

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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\* & \* document member of the same patent family

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KUSKE C R ET AL: "Small-scale DNA sample preparation method for field PCR detection of microbial cells and spores in soil" APPLIED AND ENVIRONMENTAL MICROBIOLOGY, WASHINGTON,DC, US, vol. 64, no. 7, July 1998 (1998-07), pages 2463-2472, XP002226433 ISSN: 0099-2240	1-5,9-14
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>BELANGER SIMON D ET AL: "Rapid detection of Shiga toxin-producing bacteria in feces by multiplex PCR with molecular beacons on the smart cycler"</p> <p>JOURNAL OF CLINICAL MICROBIOLOGY, WASHINGTON, DC, US, vol. 40, no. 4, April 2002 (2002-04), pages 1436-1440, XP002261197 ISSN: 0095-1137 page 1437, left-hand column</p> <p>-----</p>	1-3,9-14
A	<p>COURTNEY B C ET AL: "Development of internal controls for probe-based nucleic acid diagnostic assays."</p> <p>ANALYTICAL BIOCHEMISTRY. 1 JUN 1999, vol. 270, no. 2, 1 June 1999 (1999-06-01), pages 249-256, XP002283641 ISSN: 0003-2697 page 255, right-hand column - page 256, left-hand column</p> <p>-----</p>	1-32

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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